REMARKS

Claims 44-54 are pending. No new matter has been added by way of the present amendments. For instance, claim 46 has been amended to provide proper antecedent basis for the "biological activity" of the subunit. Additionally, claim 48 has been amended to indicate that the substance to be screened is a chemical compound. Support for this amendment may be found in the present specification, for instance, see page 7, lines 9-19, in particular, line 18. Accordingly, no new matter has been added.

Applicants further submit that no new issues have been raised by way of the present submission which would require additional search and/or consideration on the part of the Examiner. Applicants have simply amended claims 46 and 48 in order to remove a rejection under 35 U.S.C. §112, second paragraph and an objection, respectively. Thus, no new issues have been raised.

In the event that the present submission does not place the application into condition for allowance, entry thereof is respectfully requested as placing the application into better form for appeal.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. §101

The Examiner has rejected claims 44-54 under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 1-5, 31-36, 41, 54 and 58-61 of prior U.S. Patent No. 6,518,021. Applicants respectfully traverse this rejection.

As a preliminary matter, Applicants point out that the Examiner has indicated that the present claims are identical to claims of prior issued U.S. Patent 6,518,021. However, at the same time the Examiner has indicated that the present claims are anticipated by a particular prior art reference. The rationale taken by the Examiner is seemingly inconsistent.

Regardless of the above, Applicants respectfully submit that the invention as currently claimed and the invention as claimed in U.S. Patent 6,518,021 (the '021 patent) are not identical. To exemplify this point, Applicants provide the following discussion concerning why the claims of the '021 patent are not of the same scope as the present claims. In short, the method in the '021 patent utilizing a "component of an intracellular pathway" does not always provide the same results as the presently claimed method utilizing "a subunit of a component of an intracellular pathway."

First, the specification of the present application clearly indicates that a "subunit of a component" is distinct from "a component." In the Examples, several constructs are prepared where, for example, a complete, functional protein is fused directly to GFP, but in other Examples, subunits of such complete proteins are used as the fusion partners to GFP. Furthermore, the section "Background of the Invention" discusses protein kinase distribution, in the 5th paragraph, and a clear distinction is made between a "protein kinase" and a "subunit thereof." Based upon this alone, it is clear that a "subunit" of a component is distinct from "a component", just as a species is distinct from a genus.

Second, to clarify, a "component of an intracellular pathway" is a fully functional protein (cf., e.g., Examples 8 and 9, where the complete p38 and jnk1 genes, respectively, are fused to genes encoding fluorescent proteins). In contrast, a "subunit of a component" is a polypeptide

which is part of a fully functional heteropolymeric protein (cf., e.g., Example 15 relates to a fusion between a gene encoding a subunit of the p13-kinase fused to a gene encoding a fluorescent protein).

Third, it is not uncommon that protein subunits are shared by more than one protein, meaning that redistribution of such a subunit will differ from redistribution of one of the complete proteins. A well-known example of such "subunit sharing" is the case of the pituitary hormones LH, FSH and TSH, which all share the same alpha subunit but are distinguished from each other by their beta-subunits. The alpha and beta subunits are encoded by different genes on different chromosomes. Moreover, tagging the beta-subunit with a fluorescent probe would allow for study of each hormone's individual behaviour, whereas tagging of the alpha-subunits would allow for a study of the behavior of all three hormones as a response to a single stimulus. Similar situations cannot in any way be ruled out to exist for components of intracellular pathways.

Fourth, for multimeric proteins, it cannot be ruled out that the study of the redistribution of one single subunit may differ from the redistribution of a different subunit, simply because the two subunits may be under the control of different promoters or other genetic elements. Hence, the study of one subunit may reveal different mechanisms than the study of another subunit.

Fifth, step (a) in claims 44-46 and claims dependent thereon does not read on the same subject matter as that of seemingly similar claims in the '021 patent, because only the choice of a fusion construct including a subunit *uniquely tied* to the expression of one component of an intracellular pathway would provide the same technical result as use of a fusion construct including the full-length gene (in cases where that is at all possible).

In view of the above, Applicants respectfully submit that there is no issue under 35 U.S.C. §101. Reconsideration and withdrawal thereof are respectfully requested.

Issues under 35 U.S.C. §102(b)

The Examiner has rejected claims 44-54 under 35 U.S.C. §102(b) as being anticipated by Carey et al. (J. Cell Biol., June 1996). Applicants respectfully traverse.

Carey relates to a study of nuclear transportation, where a glucocorticoid receptor (GR) is fused to GFP and the resulting chimeric GR-GFP chimera is used as a marker in order to determine the function of the RAN/TC4 GTPase. However, Carey fails to disclose a method for detecting a biologically active substance as required by the present claims. This is not surprising in view of the fact that Carey is not interested in screening for substances. The Examiner's attention is directed in particular to the failure of Carey to suggest or disclose a method including a step corresponding to step (b) of the presently claimed invention.

Step (b) of the presently claimed invention requires that the cell or cells including the chimera between the subunit and the luminophore are incubated with a substance *"...to be screened for biological function or biological effect... ."*

Carey does not screen substances for their biological function or effect. Rather, in Carey the "substance" with which cells are incubated is dexamethasone; however, this substance (a glucocorticoid) already has a known effect on the glucocorticoid receptor and it is thus demonstrated that RAN/TC4 GTPase is involved in translocation. Carey thus demonstrates that "...the GR-GFP fusion protein translocates into the nucleus upon exposure to agonist [...] with kinetics similar to those published for the glucocorticoid receptor..." (page 986, line 49 ff).

However, there is no indication that a GR-GFP would be suitable for screening of substances having a biological function or biological effect.

In view of the above, Applicants respectfully submit that there exists significant patentable distinctions between the present invention and the disclosure of Carey. Accordingly, there exists no anticipation. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Issues under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 46 and 48-54 under 35 U.S.C. §112, second paragraph for the reasons recited at page 7 of the outstanding Office Action. Applicants respectfully traverse.

The Examiner has rejected claim 46 in particular asserting that the limitation "enzymatic activity" in the last two lines lacks antecedent basis. Applicants respectfully traverse and submit that claim 46 has been amended to recite "biological activity." Accordingly, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Objection to Claim 48

The Examiner has objected to claim 48 under 37 C.F.R. §1.75(c) asserting that it fails to further limit the subject matter of a previous claim. Applicants respectfully traverse and submit that claim 48 has been amended to refer to a chemical "compound." As an example, such a chemical compound is distinct from a "protein." Thus, claim 48 further limits the claims upon which it depends. Reconsideration and withdrawal of this objection are respectfully requested.

In view of the above, Applicants respectfully submit that the present claims define allowable subject matter. Accordingly, the Examiner is respectfully requested to withdrawal all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By #42,874

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